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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,112

12/29/2003

Sanjay D. Khare

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1751

22852

7590

03/01/2007

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

03/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/748,112

Applicant(s)

KHARE, SANJAY D.

Examiner

Prema M. Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-165 is/are pending in the application.
- 4a) Of the above claim(s) 1-103, 105-109, 111, 112, 117, 118 and 122-165 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 104, 110, 113-116, 119-121 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Applicants have elected Group 58 (claims 104, 110, 113-121) and the disease condition “rheumatoid arthritis” as the species of the disease condition in the response filed 12/26/2006.

However, upon further consideration it was determined that (a) a method of treating inflammation with an AGP3 inhibitor and a TNF- $\alpha$  inhibitor selected from at least one of etanercept, infliximab and D2E7, is patentably distinct from (b) a method of treating inflammation with a BAFFR inhibitor and a TNF- $\alpha$  inhibitor selected from at least one of etanercept, infliximab and D2E7, is patentably distinct from (c) a method of treating inflammation with a TAC1 inhibitor and a TNF- $\alpha$  inhibitor selected from at least one of etanercept, infliximab and D2E7. A further restriction of the elected invention into these three Groups follows:

#### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:  
  
Group 58. Claims 104, 110, 113-116, 119-121 are drawn to a method for treating rheumatoid arthritis by administering an AGP3 inhibitor and a TNF- $\alpha$  inhibitor selected from at least one of etanercept, infliximab and D2E7, Class and subclass undeterminable.  
  
Group 117. Claims 104, 110, 113-116, 119-121 are drawn to a method for treating rheumatoid arthritis by administering a BAFFR inhibitor and a TNF- $\alpha$  inhibitor selected from at least one of etanercept, infliximab and D2E7, Class and subclass undeterminable.

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Group 118. Claims 104, 110, 113-116, 119-121 are drawn to a method for treating rheumatoid arthritis by administering a TAC1 inhibitor and a TNF- $\alpha$  inhibitor selected from at least one of etanercept, infliximab and D2E7, Class and subclass undeterminable.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 58, 117-118, are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. For example, invention 58 requires search and consideration of therapeutic efficacy of administering an AGP3 inhibitor and a TNF- $\alpha$  inhibitor selected from at least one of etanercept, infliximab and D2E7 in the treatment of rheumatoid arthritis, while invention 117, for example, requires search and consideration of a method of treating rheumatoid arthritis by administering a BAFFR inhibitor and a TNF- $\alpha$  inhibitor selected from at least one of etanercept, infliximab and D2E7. Therefore, a search and examination of all the methods in one patent application would result in an undue burden because an AGP3 inhibitor is different from a BAFFR inhibitor since each of the AGP3 and BAFFR receptors are structurally disparate receptors and a search for an inhibitor to the AGP3 receptor would not reveal art for an inhibitor to the BAFFR receptor.

Furthermore, the inventions are independent and distinct, each from the other, because the methods are practiced with materially different products, which are structurally and chemically different, the novelty of the inventions lying in the products being administered and not the processes. For example, in Groups 58, 117-118, the only feature in common in the instant

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inventions is “a method of treating rheumatoid arthritis”, which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as an antibody to TNF- $\alpha$ . Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of an AGP3 inhibitor with rheumatoid arthritis would not necessarily reveal art for an association of a BAFFR inhibitor or a TAC1 inhibitor with rheumatoid arthritis.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*

Prema Mertz Ph.D., J.D.

Primary Examiner

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February 27, 2007